Growth Hormone Deficiency (GHD)

“What may help my child grow?”
“What is GHD?”
“What causes GHD?”
“How can GHD be treated?”

Your questions answered.

Indication
ZOMACTON™ [somatropin (rDNA origin)] for Injection is a prescription growth hormone product for the treatment of growth failure in children who do not make enough growth hormone on their own. This condition is called growth hormone deficiency.

Select Important Safety Information
ZOMACTON™ is contraindicated in patients with a known sensitivity to benzyl alcohol and metacresol, patients with closed epiphyses, diabetic retinopathy, active malignancy, acute critical illness, and Prader-Willi syndrome.

The following adverse reactions have been observed: headaches (children and adults), gynecomastia (children), and pancreatitis (children and adults).

Please see additional Important Safety Information continued on pages 14-16 of this brochure and accompanying Full Prescribing Information.
Understanding Growth Hormone Deficiency

A diagnosis of growth hormone deficiency (GHD) can come with so many questions for you and your child. But it’s also an answer. And once you understand more about GHD, its causes, and how you can treat it, you can begin to feel more confident that you’re armed with the knowledge, treatment, and support you need to help your child on the journey to growth.

“How does a body grow?”

The Endocrine System, Glands, and Hormones

To help you understand the growth process, here is a simple description of what goes on inside a child’s body to make it grow.

Growth (along with many other functions) is controlled by the endocrine system. The endocrine system is a network of glands and organs that communicate with each other—and with the rest of the body—by releasing chemicals called hormones.¹

The pituitary gland is a pea-sized organ near the base of the brain. It is often called the “master gland” because it produces many hormones that control various processes in your body. The pituitary gland produces growth hormone (GH).¹²

GH plays an important role in the body, especially in developing children. It’s key to normal growth and metabolism.³

**How GH Affects Growth**

GH triggers the release of insulin-like growth factor-1 (IGF-1). This hormone circulates throughout the body and causes cartilage cells to grow, which results in bone growth. It also promotes the growth of muscle and other tissues.³

**How GH Affects Metabolism**

Metabolism is the body’s natural process of converting food into energy and waste products. GH affects this process in several ways. It encourages your body to use more amino acids, which creates more proteins. It helps maintain proper levels of carbohydrates in the body and stimulates the use of fat (stored energy) by breaking down triglycerides.³
"Why do some bodies not grow properly?"

Defining Growth Hormone Deficiency

Simply put, a child with GHD is not producing enough growth hormones for normal development. GHD is a condition that affects both boys and girls. In fact, there are an estimated 1 in 4,000 to 10,000 children who have GHD.\(^4\)

GHD may occur by itself or in combination with other hormone deficiencies. And there are different degrees of GHD. **Total GHD** means that no growth hormone is produced at all. If some growth hormone is produced, but not enough for normal growth, it is called **partial GHD**.\(^5\)

Some causes of GHD are **Congenital**, **Acquired**, and **Other**.

**Congenital GHD**
"Congenital GHD" means that the child has been born with this condition. From birth, the endocrine system doesn’t work properly to encourage normal growth. This may be the result of something that happened while the child was in the womb, such as an injury or other complication. Congenital GHD may not be noticeable for months.\(^5\)

**Acquired GHD**
Damage to the pituitary gland or other important parts of the endocrine system after birth can result in "acquired GHD." Serious illness, exposure to radiation therapy or a head injury can result in GHD at any time. Often, a tumor affecting the hypothalamus or pituitary gland will cause acquired GHD. But even if the tumor is removed, it may not correct the degree of GHD.\(^5\)

**Other Impacts on Growth**
There are other factors besides GHD that may impact a child’s growth. Poor nutrition, more than anything, may prevent a child from growing at a normal rate. A balanced diet is essential to the healthy development of growing children. However, even if a child eats a balanced diet, growth problems can still occur if the food is not absorbed and metabolized properly.\(^5,6\)

**Discovering Treatment Options**
Remember: Although in many cases no cause can be found for GHD, now you can get help—by working with your doctor to get the proper treatment and support.
“How can growth hormone replacement therapy help?”

Your Doctor Has Recommended Growth Hormone Replacement Therapy

You and your doctor have decided to treat your child’s Growth Hormone Deficiency (GHD) with ZOMACTON™ [somatropin (rDNA origin)] for Injection. ZOMACTON™ is a prescription growth hormone product for the treatment of growth failure in children who do not make enough growth hormone on their own.

ZOMACTON™ has been approved by local health authorities outside of the United States to treat GHD since 1988 in 47 countries around the world.1,4

With human growth hormone (hGH) therapy like ZOMACTON™, your child may reach a height similar to that of other children his or her age. Not everyone responds to hGH therapy in the same way. However, today most children receiving replacement therapy reach a normal adult height consistent with the average height of others in their family. The sooner your child begins treatment, the more successful therapy is likely to be.4,5

Beginning GH Therapy
GH therapy with ZOMACTON™ only works when injected. Your doctor will prescribe injections for your child, based on weight, that will have to be given three (3) times a week.

The recommended dosage of up to 0.1 mg/kg of body weight administered subcutaneously (under the skin/injected) three (3) times per week (up to 0.3 mg/kg/week). Please refer to the ZOMACTON™ Prescribing Information or your doctor for complete dosing information.

ZOMACTON™ is available in 5-mg and 10-mg vials. Your doctor will decide whether 5 mg or 10 mg will be best for your child.

Select Important Safety Information
WHO SHOULD NOT TAKE ZOMACTON™?

- Benzyl alcohol, a component used to reconstitute the ZOMACTON™ 5-mg vial, should not be used with newborns. Benzyl alcohol has been associated with serious adverse events and death. When administering ZOMACTON™ 5 mg to newborns, it should be reconstituted with sterile normal saline. Benzyl alcohol should not be used in patients with a known sensitivity.
- You should not take ZOMACTON™ if you are allergic to any of the ingredients in the medicine. Serious allergic reactions have occurred in patients taking somatropin products. ZOMACTON™ 10-mg vial is reconstituted with bacteriostatic water for injection containing metacresol; therefore, ZOMACTON™ should not be used by patients allergic to metacresol. If you develop any allergic reaction after an injection of ZOMACTON™, seek medical attention promptly.

Please see Indication, Important Safety Information on pages 14-16 of this brochure and accompanying Full Prescribing Information.
“What if I have questions about treatment or insurance?”

The ZoGo Support Program Can Help

Your doctor’s office staff will enroll eligible patients in the ZoGo Support Program and let the ZoGo team know your child is being prescribed ZOMACTON™. Our team of professionals is with you every step of the way, 24 hours a day, seven days a week. Patients must meet eligibility requirements to access certain Program benefits. Please contact the ZoGo Support Program at 844-944-ZOGO (9646). You’ll get a welcome phone call to answer any immediate questions and a complete Welcome Kit with tools and information about GH therapy and ZOMACTON™. In addition, one of our specially trained nurses will come to your home to teach you and/or your caregiver how to safely and correctly give your child ZOMACTON™ injections.

But it doesn’t stop there. The ZoGo Support Program team will help make sure your shipment of ZOMACTON™ is received and even coordinate insurance coverage with your pharmacy. There are also special ZOMACTON™ financial assistance programs that you may qualify for as well. The ZoGo Support Program team can help you with that, too.

Throughout treatment, the ZoGo Support Program team will continue to be your contact for information, insurance coverage, and refills. Thanks to ZoGo, with ZOMACTON™ treatment you’ll never have to go it alone.

Please see Indication, Important Safety Information on pages 14-16 of this brochure and accompanying Full Prescribing Information.
“What should we expect from GH therapy?”

Treatment With ZOMACTON™ [somatropin (rDNA origin)] for Injection

Your physician will monitor your child’s response to ZOMACTON™. It’s possible your child may experience side effects; if he or she does experience any side effects, you should talk to your doctor immediately. We’ve included Important Safety Information on pages 14-16 of this brochure. You can also refer to the accompanying Full Prescribing Information.

The First Few Months
As you begin treatment, there is sometimes a sudden “spurt” in growth rate. This fast increase may be noticeable to you and your child within 3 to 4 months. Eventually, growth should progress more slowly, but remain steady.7

Stay the Course
If this sudden growth spurt doesn’t occur, or once it has tapered off, you and your child may become impatient and expect faster results. Don’t become discouraged or give up. Stay on track. Stick to the plan and dosing schedule provided by your doctor. NEVER increase the dose or number of injections unless specifically instructed to do so by your doctor.

Be Positive
You should see results over time. But, remember that growth is a slow process measured over many months and possibly years. If your child expects to grow suddenly overnight after starting treatment, he or she will be disappointed. Your doctor will discuss realistic short- and long-term expectations with you and will determine how long you will remain on GH. Treatment may last into the late teens or early adulthood. It’s important that you explain all this to your child, and remind your child (and yourself) to be patient.5 Good communication during this journey is crucial to help your child to keep a positive outlook.5

Please see Indication, Important Safety Information on pages 14-16 of this brochure and accompanying Full Prescribing Information.
“How can I help my child throughout treatment?”

Positive Support for Children With GHD

Remember, smaller doesn’t mean younger. And just because your child is small in size doesn’t mean he or she should be treated as if he or she were younger. For children with GHD to mature and grow emotionally, they need to be treated like children their own age. This can sometimes be hard for other children, and even adults may treat a small child as if he or she was younger. It’s important for you to talk to your child about this. Provide encouragement, praise any accomplishments, and boost their confidence whenever you can. It’s also important to talk to your child’s teachers and classmates. Help them understand a little bit about GHD and ask for their help in keeping your child positive.

Getting the Results
Treatment for children with GHD is a journey. It’s not always easy for them, or for you. But, if you and your child can keep a positive attitude, the results may be satisfying. For more information, visit zomacton.com or call 1-844-944-ZOGO (9646).

Please see Indication, Important Safety Information on pages 14-16 of this brochure and accompanying Full Prescribing Information.

References
**ZOMACTON™ [somatropin (rDNA origin)] for Injection**

**Indication**

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- You should not take ZOMACTON™ if you are allergic to any of the ingredients in the medicine. Serious allergic reactions have occurred in patients taking somatropin products. ZOMACTON™ 10-mg vial is reconstituted with bacteriostatic water for injection containing metacresol; therefore, ZOMACTON™ should not be used by patients allergic to metacresol. If you develop any allergic reaction after an injection of ZOMACTON™, seek medical attention promptly.

- ZOMACTON™ should not be used in children whose growth plates in their bones have closed (closed epiphyses).

- ZOMACTON™ should not be used in diabetic patients with certain types of eye problems (diabetic retinopathy).

- ZOMACTON™ should not be used if you have active cancer. Because growth hormone deficiency can be an early sign of some tumors in the brain or pituitary gland, the presence of these types of tumors should be ruled out by your doctor before you start ZOMACTON™.

- You should not take ZOMACTON™ if you are having serious complications after undergoing open heart surgery, abdominal surgery, serious injuries involving many body systems, or life-threatening breathing problems. Deaths have been reported in such cases.

- Growth hormone should not be used in children with Prader-Willi syndrome who have severe obesity or have a history of severe breathing problems. Deaths have been reported in children with Prader-Willi syndrome who are severely obese or who have a history of blocked upper airways, sleep apnea (pauses in breathing during sleeping), or other severe breathing problems. ZOMACTON™ has not been approved for the treatment of pediatric patients with Prader-Willi syndrome.

**WHAT SHOULD I TELL MY DOCTOR BEFORE OR WHILE TAKING ZOMACTON™?**

- Tell your doctor if you have Prader-Willi syndrome. There have been reports of death in children with Prader-Willi syndrome who recently started growth hormone therapy and had one or more of the following risk factors: obesity, history of severe breathing problems or sleep apnea (pauses in breathing during sleeping), unidentifiable respiratory infection, boys with one or more of these risk factors may be at greater risk than girls. A child with Prader-Willi syndrome should be evaluated by a doctor for signs of severe breathing problems or sleep apnea before starting growth hormone therapy.

- Seek prompt medical attention for any allergic reaction you experience to the injection of ZOMACTON™. Potentially life-threatening anaphylaxis (allergic reaction) and angioedema (swelling below the surface of the skin) have been reported with the use of growth hormone products.

- Tell your doctor if you have a history of pancreatitis before taking ZOMACTON™. Cases of pancreatitis (inflammation of the pancreas) have been reported rarely in children and adults receiving growth hormone. Consult a doctor if you develop abdominal pain while taking ZOMACTON™.

- In childhood cancer survivors, treatment with growth hormone may increase the risk of developing a new tumor, especially in the brain. If you had cancer as a child and received radiation treatment to your head, you may have a greater risk of developing a new tumor if you are treated with growth hormone. The most common type of tumor reported in people treated with growth hormone after radiation to the head was a tumor of the covering of the brain, called a meningioma. If you developed growth hormone deficiency because you had a tumor inside the head or received radiation to the head, you should be monitored closely by your doctor during treatment with growth hormone. Children who have some rare genetic conditions may have a greater risk of developing a tumor if treated with growth hormone. If you have moles/beauty marks on your skin, you should have these checked carefully for any changes while being treated with growth hormone.

- Your doctor should check your blood sugar regularly while you are taking ZOMACTON™, especially if you have risk factors for diabetes. If you have diabetes or impaired glucose tolerance, your doctor should monitor your blood sugar closely during ZOMACTON™ therapy. New cases of type 2 diabetes mellitus have been reported in patients taking somatropin.

- If you have hypoadrenalism, and are on glucocorticoid replacement therapy, your doctor may increase your dose when you first start on growth hormone.

- You should have your thyroid function tested periodically during ZOMACTON™ therapy. Thyroid hormone treatment may need to be started or adjusted.

- Slipped capital femoral epiphysis (fracture in the ball of the hip joint) can occur in children who have endocrine problems and in children who have rapid growth. Any child taking ZOMACTON™ who develops a limp or complains of hip or knee pain should be seen by a doctor to check for slipped capital femoral epiphysis.

- Tell your doctor if you have any visual changes accompanied by headache, nausea, and/or vomiting while taking ZOMACTON™. This may be a sign of increased pressure in the brain.

- Progression of scoliosis (curvature of the spine) can occur in children who have rapid growth.

- You should rotate your injection sites to avoid breakdown of skin and fat.

- ZOMACTON™ may affect how other medicines work, and other medicines may affect how ZOMACTON™ works, so be sure to tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take glucocorticoid medication, thyroid hormone, insulin or other medicine for diabetes, medicines that are metabolized by the liver (e.g., corticosteroids, sex steroids, anticonvulsants, cyclosporine), or oral estrogen replacement medicine.

- If you are pregnant or nursing, you should talk to your doctor before using ZOMACTON™. It is not known whether ZOMACTON™ is excreted in human milk. ZOMACTON™ should be used during pregnancy only when clearly needed.

**Important Safety Information continued on the next page.**
Important Safety Information (continued)

WHAT ARE THE POSSIBLE SIDE EFFECTS OF ZOMACTON™?

• Common side effects reported in adults and children taking ZOMACTON™ include headaches, enlarged breast tissue (gynecomastia), and inflammation of the pancreas (pancreatitis). Other side effects might include injection site reactions (such as pain, numbness, redness, and swelling), allergic reactions (some may be serious) to the product or any of its ingredients, and low levels of thyroid hormone (hypothyroidism). Leukemia and new-onset type 2 diabetes mellitus have been reported in patients treated with growth hormone therapy. Potentially life-threatening anaphylaxis (allergic reaction) and angioedema (swelling below the surface of the skin) have been reported with the use of growth hormone products and require immediate attention.

• You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 800-FDA-1088.

HOW SHOULD I STORE ZOMACTON™?

• ZOMACTON™ must be kept refrigerated (36°F to 46°F [2°C to 8°C]). DO NOT FREEZE. After mixing with liquid, ZOMACTON™ 5 mg must be used within 14 days and ZOMACTON™ 10 mg must be used within 28 days. Do not use if it has expired. Do not inject medication if it is cloudy.

Please see accompanying Full Prescribing Information for ZOMACTON™.
**ZOMACTON** (somatropin) for injection

**RECEIPT**

ZOMACTON is a white to slightly yellowish lyophilized, sterile, water-for-injection product, with no visible particulate matter, which is reconstituted with 1 mL of bacteriostatic water for injection containing 0.33% metacresol. In the reconstituted solution, somatropin has a molecular weight of approximately 22,124 daltons. 

**INDICATIONS**

ZOMACTON is indicated for the treatment of growth hormone deficiency in children, including those with Prader-Willi syndrome. 

**CLINICAL PHARMACOLOGY**

**Mechanism of Action**

Somatropin is a synthetic form of human growth hormone. It is used to treat growth hormone deficiency in children, including those with Prader-Willi syndrome. 

**Pharmacokinetics**

Somatropin is rapidly absorbed after subcutaneous administration and has a short half-life of approximately 2-3 hours due to rapid degradation by circulating enzymes. The terminal elimination half-life is approximately 2-3 hours. 

**ADVERSE REACTIONS**

The most common adverse reactions associated with somatropin treatment include injection site reactions, headache, and joint pain. 

**CONTRAINDICATIONS**

Somatropin is contraindicated in patients with active malignancy, including reticuloendotheliosis, and in patients with a history of upper airway obstructions or sleep apnea. 

**PRECAUTIONS**

Somatropin treatment should be discontinued if there is evidence of recurrent activity. Since growth hormone deficiency may be an early sign of the presence of a pituitary tumor (or, rarely, other brain tumors), the presence of such tumors should be excluded prior to instituting therapy with somatropin. 

**DRUG INTERACTIONS**

Somatropin has been shown to increase the clearance of certain drugs, including corticosteroids, allopurinol, and lithium. 

**PREGNANCY**

Somatropin has not been shown to cause harm to the fetus. 

**NURSING MOTHERS**

Somatropin has not been evaluated in nursing mothers. 

**REFERENCES**

For complete details, please refer to the full Prescribing Information.
Preparing for Your ZOMACTON Injection

- Place the supplies you will need on a clean, flat surface in a well-lit area.
- Use the 10mg liquid with the 10mg ZOMACTON.
- Do not use the 5mg liquid with the 10mg ZOMACTON.
- California residents: To obtain information about your or your child’s medical condition or treatment, call the manufacturer’s patient support number at 1-800-676-8705 (24 hours a day, 7 days a week).

Checking an Injection Site

- Two or different sites can be used for your injections. These sites should be rotated (See Figure K).

Mixing ZOMACTON

- Shake the vial gently (See Figure Q) to make sure the liquid is mixed evenly.
- Do not shake vigorously.

Step 1: Preparing the Injection

- Remove the needle cap from the syringe filled with liquid and insert the needle into the center of the rubber stopper on the growth hormone vial (See Figure M).
- Recap the needle.

Step 2: Choosing an Injection Site

- Choose a site with firm, fatty tissue that is far away from any hard bone (See Figure N). Do not inject ZOMACTON into the same site twice in one day.

Step 3: Injecting ZOMACTON

- With your free hand, pinch the skin around the site with the thumb and forefinger of the other hand (See Figure T). This will help prevent aspiration of subcutaneous fluid into the syringe.
- Using a circular motion, clean the injection site with an alcohol swab, starting at the injection site and moving outward about 2 inches. Let the area air dry (See Figure R).
- Do not throw used needles, syringes, or vials in your household trash or recycle.

Step 4: Disposing of used syringes, needles, and vials

- To prevent needle-stick injury and spread of infection, do not try to re-cap the needle.
- Follow your local, state, and federal laws and regulations about how you should throw away used needles and syringes.
- If you do not use a FDA-cleared sharps disposal container, you may use a household container that is:
  - Made of a heavy-duty plastic,
  - Can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - Upright and stable during use,
  - Made of a leak-resistant, and
  - Can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
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  - Can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,

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Manufactured for:
Ferring Pharmaceuticals Inc., Parsippany, NJ 07054
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